US ERA ARCHIVE DOCUMENT

DATE:

August 14, 1984

SUBJECT:

EPA Registration Number 524-316

Alachlor

FROM:

Deloris F. Graham Fred 129/84

E 8/29/84

TO:

Robert Taylor

Product Manager (25)

Applicant: Monsanto Agricultural Products Co.

800 N. Lindbergh Boulevard

St. Louis, MO 63167

Active Ingredient:

Inert Ingredients:....

Background: Submitted Dermal Sensitization Study. Study conducted by Bio/dynamics Inc. Study under accession number 252772. Method of support not indicated.

## Recommendation:

- (1) FEB/TSS finds these data acceptable to support conditional registration of this product.
- (2) Dermal Sensitization Study indicates that this product is a potential skin sensitizer.

## Label:

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(1) No additional label comments.

## Review:

(1) Dermal Sensitization Study: Bio/Dynamics, Inc. Project No. 4030-82); April 13, 1982.

Procedure: Five male and five female Hartley guinea pigs with shaved backs received 0.2 ml of the test material using the closed patch technique. Applications were made for six hours per day, three days per week for three weeks, the induction phase. Two weeks after final dose, additional 02 ml of the test matter was applied, challenge dose. A group of three male and three female guinea pigs served as main control hogs. Two additional groups were treated with 1-chloro-2,4-dinitro-benzine (DNCB) in ethanol, a positive control. A fifth group of 5N and 5F guinea pigs were treated with forth indication and challenging satin doses. These animals served as negative controls. Observations made at 24 and 48 hours after dosing, twice daily for mortality and weekly for signs of toxicity.

Results: Irritation noted during indication period in test animals. In several instances it was noted that irritation became severe after fourth or fifth treatment. At challenge dose all ten animals exhibited dermal irritation. Edema and necrosis were also noted.

All ten treated with DNCB exhibited dermal irritation in response to challenge dose of non-irritating concentration of DNCB, thereby effectively identifying delayed hypersensitivity when a known skin sensitizer is used.

No irritation noted in negative controls.

Study Classification: Core Guideline Data.

Toxicity Category: Potential Skin Sensitizer.